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10/750,586

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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PAENT APPEALS
AND INTERFERENCES

Ex parte MARTIN R. WILLARD
and
PU ZHOU

Appeal 2008-2157
Application 10/750,586¹
Technology Center 1700

Decided: May 02, 2008

Before ADRIENE LEPIANE HANLON, CAROL A. SPIEGEL, and
LINDA M. GAUDETTE, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Application 10/750,586 ("the 586 application"), titled "Catheter Incorporating an Improved Polymer Shaft," filed 29 December 2003, is said to be a continuation-in-part of application 10/377,457, filed 28 February 2003, which claims benefit of the 28 February 2002 filing date of provisional application 60/361,229. The real party-in-interest is said to be Boston Scientific Scimed, Inc. (Amended Appeal Brief filed 10 August 2007 ("App. Br.") 3).

I. Statement of the Case

Martin R. Willard and Pu Zhou ("Appellants") appeal under 35 U.S.C. § 134 from the final rejection of claims 28-43. Claims 26-27, the only other pending claims, have been withdrawn from consideration. [App. Br. 3; Ans.² 2]. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

The subject matter on appeal relates to a catheter shaft having proximal, intermediate, and distal portions made of defined polymeric blends. Claim 28 is illustrative and reads (App. Br. 8, emphasis added):

28. A catheter shaft, including a polymer blend shaft, comprising:

*a proximal portion having about 80 to about 95 weight % polyoxymethylene **homogeneously blended** with about 5 to about 20 weight % polyether polyester;*

an intermediate portion coupled to the proximal portion, the intermediate portion having about 20 to about 50 weight % polyoxymethylene and about 50 to about 80 weight % polyether polyester and a uniform wall thickness; and

a distal portion coupled to the intermediate portion, the distal portion having about 5 to about 20 weight % polyoxymethylene and about 80 to about 95 weight % polyether polyester.

The Examiner relies on the following references³ as evidence of unpatentability:

Utsumi	US 5,258,160	Nov. 2, 1993
Itou	EP 1 068 876 A2	Jan. 17, 2001

² Examiner's Answer mailed 24 September 2007 ("Ans.").

³ No references to *et al.* are made in this opinion.

The Examiner finally rejected claims 28-43 under 35 U.S.C. § 103(a) as unpatentable over the combination of Itou and Utsumi (FR⁴ 3; Ans. 3).

Appellants argue that neither Itou nor Utsumi teach or suggest "a proximal portion having about 80 to about 95 weight % polyoxymethylene *homogeneously blended* with about 5 to about 20 weight % polyether polyester" as required by all the claims on appeal and, therefore, no *prima facie* case of obviousness exists (App. Br. 5). Since this is the only patentability argument raised by Appellants, all the appealed claims stand or fall together. Therefore, we decide this appeal on the basis of claim 28. 37 C.F.R. § 41.37(c)(1)(vii).

II. Findings of Fact ("FF")

The following findings of fact and those set out in the Discussion are supported by a preponderance of the evidence of record.

A. The 586 application

- [1] According to the 586 specification, since diagnostic and guide catheters commonly navigate through vascular anatomy, catheter shafts have been developed with desirable torqueability, trackability, and pushability characteristics (Spec. 1:12-19).
- [2] The 586 specification describes catheter shafts made of polymer blends, e.g.,

[T]he polymer blend may include polyoxymethylene blended with a polymer group having an ether group, for example, polyether polyester. In some embodiments, the shaft may include a proximal portion, an intermediate portion, and a distal portion. Each portion may have the same or differing proportions of

⁴ Final Office Action mailed 10 January 2007 ("FR").

polyoxymethylene. The shaft may also include an inner layer and an outer layer, each of which may have the same or differing proportions of polyoxymethylene. [Spec. 2:3-9.]

- [3] The flexural modulus or rigidity of a portion may be controlled by altering the proportion of polyoxymethylene and polyether polyester in the portion (Spec. 6:4-10).
- [4] The polymer blended portions may be manufactured by "extrusion of a polyoxymethylene pre-blend or by co-extrusion of the polyoxymethylene with the polyether polyester such as by interrupted layer co-extrusion" (Spec. 6:14-16).
- [5] Alternatively, the proximal, intermediate, and distal portions may be formed of separately extruded tubular segments which are subsequently fused together (Spec. 6:16-18).

B. Itou

- [6] Itou discloses a catheter 1 comprising a tubular member or shaft 22 divided into a proximal portion 221, an intermediate portion 222, and a distal portion 223 (Itou 6:36-43; Fig. 1).
- [7] In one embodiment, manufacture of the catheter comprises preparing a first linear member 51 made of a first resin material and a second linear member 52 made of a second resin material (Itou 2:19-26),

rotating the supply source of the first linear member and the supply source of the second linear member around the tubular member and . . . adjusting the relative rotating speeds of the supply sources . . . to adjust the disposing densities of the first and second linear members on the tubular member (*id.*, 2:49-56),

- and, desirably, at least partially melting the first and second linear members to achieve mixing or fusing, followed by cooling to form a flat resin layer (*id.*, 3:2-6; 8:35-42).
- [8] Adjusting the disposing densities of the resin materials allows the flexural rigidity of the catheter to be gradually diminished from the proximal end of the catheter toward its distal end (Itou 5:20-24; 13:1-3).
- [9] Preferably, the first linear member/resin material has a higher flexural rigidity than that of the second linear member/resin material (Itou 2:57 through 3:1; 4:23-25).
- [10] Exemplary first and second resin materials include polyoxymethylene and polyester elastomers, such as polyether polyester, respectively (Itou 8:13-30; 11:46-53).
- [11] The ratio of the first linear member 51 to the second linear member 52 in proximal portion 221 and in distal portion 223, on a weight basis, preferably falls between 1:0.1 and 1:0.95 and between 0.1:1 and 0.95:1, respectively (Itou 10:32-43).
- [12] Heating conditions are determined in view of the materials used (Itou 15:23-26).
- [13] "During the heating, it is possible for the first linear member 51 and the second linear member 52 to be melted completely and to be solidified in a uniformly mixed or fused state" (Itou 15:29-32).
- C. Utsumi
- [14] Utsumi discloses methods and apparatuses for producing elongated bodies, e.g., medical catheters, using polymers such as polyester

elastomers for flexibility and polyoxymethylene for torque transmission (Utsumi 1:8-15; 5:57-68).

[15] "At least two of such polymers are useful in the form of a blend as adjusted to exhibit a desired flexural modulus" (Utsumi 6:3-5).

III. Principles of Law

Generally, "in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification." *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983). However, when the specification lacks a clear term definition, the language of the claims, and accordingly the scope and content of the claimed subject matter, should be interpreted as broadly as the specification will otherwise reasonably allow.

A claimed invention is not patentable if the subject matter of the claimed invention would have been obvious to a person having ordinary skill in the art at the time the invention was made. 35 U.S.C. § 103(a). *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Facts relevant to a determination of obviousness include: (1) the scope and content of the prior art, (2) any differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) relevant objective evidence of obviousness or nonobviousness. *KSR*, 127 S. Ct. at 1734; *Graham*, 383 U.S. at 17-18.

IV. Discussion

The Examiner found that Itou "specifically states that the first and second materials are melted completely and solidified in a uniformly mixed or fused state (col.15, 1.29-32)" (Ans. 4) and that Itou differed from the

subject matter of claim 28 in failing "to explicitly teach that polyoxymethylene is chosen as the more rigid material and that the polyether ester is chosen as the less rigid material" (Ans. 5). The Examiner further found that Utsumi teaches that "in the art of forming catheters having a varying rigidity longitudinally throughout the catheter, polyester elastomer such as polyether ester taught by Itou . . . is . . . used as . . . the flexible material, and polyoxymethylene taught by Itou . . . is . . . used as the rigid material" (Ans. 5-6). The Examiner concluded that it would have been obvious to one of ordinary skill in the art to use polyoxymethylene and polyether polyester, respectively, as the more rigid and less rigid resin materials of Itou since each resin material is taught in the prior art for use in providing rigidity and flexibility, respectively (Ans. 6).

Appellants argue that neither Itou nor Utsumi teach or suggest "a proximal portion having about 80 to about 95 weight % polyoxymethylene *homogeneously blended* with about 5 to about 20 weight % polyether polyester" as required by all the claims on appeal and, therefore, no *prima facie* case of obviousness exists (App. Br. 5). Appellants specifically argue that "'uniformly mixed' does not compel homogeneity" (App. Br. 5).

Therefore, we begin our analysis with determining the scope of the term "homogenously mixed."

According to Appellants,

While this phrase does not appear verbatim in the specification, support can be found on page 5, lines 7-8 and page 6, lines 14-15: "Shaft 12, or sections thereof, may be manufactured from or otherwise include a polymer blend." "Manufacturing the polymer blended sections 14/16/18 may include

extrusion of a polyoxymethylene pre-blend."
[App. Br. 4.]

Thus, Appellants assert that "a mixture is either homogenously blended or it is not" (Reply Br.⁵ 2).

Here, the 586 specification does not define the term "homogeneously blended." Appellants have not directed us to evidence showing that the claim term "homogeneously blended" excludes "uniformly mixed" as disclosed by Itou (Itou 15:29-32). Attorney argument, absent evidence, is entitled to little, if any, weight. *Velandier v. Garner*, 348 F.3d 1359, 1371, (Fed. Cir. 2003); *Meitzner v. Mindick*, 549 F.2d 775, 782, (CCPA 1977). Therefore, we agree with the Examiner that "the broadest reasonable interpretation of 'homogeneously blended' would include uniformly mixed as taught by Itou" (Ans. 7).

Since Appellants have failed to show that the Examiner erred in finding that Itou taught that the polyoxymethylene and polyether ester are homogeneously blended, we affirm the rejection of claims 28-43 under 35 U.S.C. § 103(a) as unpatentable over Itou in view of Utsumi.

V. Order

Upon consideration of the record, and for the reasons given, it is

ORDERED that the decision of the Examiner rejecting claims 28-43 as obvious over Itou in view of Utsumi is AFFIRMED; and,

⁵ Reply Brief under 37 C.F.R. § 41.41 filed 20 November 2007 ("Reply Br.").

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Application 10/750,586

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 35 U.S.C. § 1.136(a) (2006).

AFFIRMED

Appeal 2008-2157
Application 10/750,586

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